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## **REMARKS**

In an Office action dated December 26, 2007, the Examiner considered pending claims 21-64, following which:

- (1) claims 26 and 31-35 stand objected to as being in multiple dependent form;
- (2) claim 35 is rejected under 35 U.S.C. § 112, first paragraph, for failing to comply the enablement requirement;
- (3) claim 58 is rejected under 35 U.S.C. § 112, second paragraph, for being dependent from an unlisted claim;
- (4) claims 21, 27, 28, 36, 37, and 39 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,368,350 to Erickson, et al. ("Erickson");
- (5) claims 21-23, 30, 34, 41, 42, 46-49, 52, 56, 57, 61, and 64 stands rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,936,071 to Marnay et al. ("Marnay");
- (6) claims 21, 22, 29, 33, 41, 47, 50, 56, 62, and 63 stand rejected under 35 U.S.C.102(e) as being anticipated by U.S. Pat. No. 6,610,093 to Pisharodi ("Pisharodi");
- (7) claims 24-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson in view of U.S. Patent No. 6, 419,706 to Graf ("Graf");
- (8) claim 40 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson in view of Pisharodi;
- (9) claim 38 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.Patent No. 6,368,350 to <u>Erickson</u>;
- (10) claims 43-45 and 58-60 stands rejected under 35 U.S.C. 103(a) as being unpatentable over <u>Marnay</u> in view of Pisharodi;
- (11) claims 54 stands rejected under 35 U.S.C. 103(a) as being unpatentable over <u>Marnay</u> in view of Graf;
- (12) claim 55 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay in view of U.S. Patent No. 6,899,735 to Coates, et al. ("Coates"); and

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(13) claims 31, 32, 51, and 53 stands rejected under 35 U.S.C. 103(a) as being

unpatentable over Pisharodi.

The Applicants respectfully submit the following remarks concerning the December 26, 2007,

Office action.

Objection to Claims 26 and 31-35

As set forth in the Amendments to the Claims and Listing of Claims sections of this

paper, claims 26, 31, and 33-35 are hereby amended. No new matter has been introduced by

such amendments, which are fully supported by the original disclosure. The amendments are

made solely to remove the multiple dependency forming the basis for the objection to claims 26

and 31-35. Withdrawal of the objection to such claims is respectfully solicited.

Rejection of Claim 35 Under 35 U.S.C. § 112, ¶ 1

Claim 35 has been amended to remove the location of the rib at the center of the

prosthesis, which is understood to be the basis of the rejection. Claim 35 is fully enabled, for

example, by the description at page 6, lines 12-18. Withdrawal of the rejection of claim 35 under

35 U.S.C. § 112, paragraph 1, is respectfully requested.

Rejection of Claim 58 Under 35 U.S.C. § 112, ¶ 2

Claim 58 has been amended to depend from claim 57. Withdrawal of the rejection of

claim 58 under 35 U.S.C. § 112, paragraph 2, is respectfully requested.

Rejection of Claims 21, 27, 28, 36, 37, and 39 Based on Erickson

Independent claim recites "cooperation means not located in the middle of the core

between the lower plate and the core, so as to limit translation movements of the core with

respect to the lower plate around an axis substantially parallel to the lower plate, and to limit or

eliminate rotation movements of the core with respect to the lower plate around an axis

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substantially perpendicular to the lower plate." The rejection based on Erickson ignores this limitation of claim 21.

Erickson does not disclose the cooperation means not located in the middle of the core required by claim 21. The Office action cites column 7, lines 65-67, of Erickson, but that passage states simply that "limiting arrangements such as raised edge 100 can be configured to limit the rotational or translational freedom provided at the planar bearing surface 51." As shown in Figures 4, 4A, 6, 7, 8, and 10, however, the raised edge 100 is not configured in a way that will limit the rotational movements of the intermediate piece 22. Nothing in Erickson discloses raised edge 100 limiting rotational movements of the intermediate piece 22. Thus, the Office action does not establish the anticipation of claim 21 by Erickson, and the rejection of claim 21 and claims 27, 28, 36, 37, and 39 depending directly or indirectly from claim 21 must be withdrawn.

## Rejection of Claims 21-23, 30, 34, 41, 42, 46-49, 52, 56, 57, 61, and 64 Based on Marnay

The reply filed in this case on October 16, 2007, fully explains why the rejections based on Marnay are unfounded and improper, and that reply is incorporated herein by reference. Rather than address the merits of the reply, though, the December 26, 2007, Office action recites that "a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations," citing Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Int. 1987). Thus, because the core and endplates of Marnay can translate and rotate before the Marnay prosthesis is assembled, the Office action concludes that Marnay discloses the structure recited in the rejected claims. Masham and this argument, however, do not apply to the claims at issue in this application or to the rejections based on Marnay.

The MPEP clearly directs that "[t]here is nothing inherently wrong with defining some part of an invention in functional terms." MPEP § 2173.05(g). According to the MPEP, "[f]unctional language does not, in and of itself, render a claim improper." <u>Id.</u> (citing <u>In re</u>

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Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971)). The MPEP gives the following example:

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as 'members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to *precisely define present structural attributes* of interrelated component parts of the claimed assembly.

Id. (citing In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976)) (emphasis added). Thus, functionally described limitations can define structural attributes. In that regard, a "functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." Id.

Like the claims at issue in <u>Venezia</u>, claims 21, 41, and 56 define structural attributes of interrelated parts of the claimed assembly. For example, claim 21 recites an:

upper plate being moveable at least with respect to the core and [a] core being movable in translation and rotation with respect to the lower plate.

These limitations define structural attributes for the upper plate, lower plate, and core, which attributes are not present in the assembled Marnay device because it lacks those structural attributes. In addition, claim 41 recites:

the lower surface of the core being configured for contact with at least part of the upper surface of the lower plate, said contact of the lower surface of the core with at least part of the upper surface of the lower plate being configured for translation movements of the core with respect to the lower plate along an axis substantially parallel to the upper surface of the lower plate and for rotation movements of the core with respect to the lower plate around an

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axis substantially perpendicular to the upper surface of the lower plate.

Again, these limitations define structural attributes for the upper plate, lower plate, and core, which attributes are not present in the assembled Marnay device because it lacks those structural attributes. In addition, claim 56 recites:

the lower surface of the core being configured for contact with at least part of the upper surface of the lower plate, said contact of the lower surface of the core with at least part of the upper surface of the lower plate being configured for translation movements of the core with respect to the lower plate along an axis substantially parallel to the lower plate and for rotation movements of the core with respect to the upper surface of the lower plate around an axis substantially perpendicular to the upper surface of the lower plate

Again, these limitations define structural attributes for the upper plate, lower plate, and core, which attributes are not present in the assembled Marnay device because it lacks those structural attributes. These limitations are not mere statements of intended use or mere functional statements. Rather, these limitations require a core and the plates to have specific structure for engaging each other in the specific ways; only cores and plates having the structural attributes required by the claims can satisfy these limitations.

Ex parte Masham is fully consistent with this analysis. The claim at issue in that case was directed to an apparatus for mixing flowing developer material in which mixing means are "completely submerged in the developer material." Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Int. 1987). The applicant argued that in the prior art apparatus, "the mixing means is depicted 'as only being partially submerged in the developer material." Nevertheless, the Board upheld the rejection based on the factual determination that the prior art disclosed all of the structural limitations of the rejected claim and that the prior art "mixing device 40 is *capable* of being totally submerged in the developer material." <u>Id.</u> (emphasis added). In stark contrast to the art relied on in <u>Masham</u>, Marnay does not disclose the structure required by claims 21, 41,

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and 56 of this application, and the Marnay prosthesis is not capable of performing as required by those claims.

The limitations of claims 21, 41, and 56, also would not fairly convey to a person of ordinary skill in this art characteristics that are present only before the prosthesis is assembled. In other words, a person of ordinary skill would not view the core and endplate of Marnay as having the recited limitations, because those limitations are not present when the Marnay device is assembled. The Office action cites no evidence to support the view that the claims should be interpreted to read on devices such as Marnay that *lack* the recited limitations when the device is assembled. Although the Office action's position to the contrary is unreasonable, to expedite the allowance of the pending claims, claims 21, 41, and 56 have been amended to recite that various arrangements are required "when the intervertebral disc prosthesis is assembled." Accordingly, a person of skill in the art could not view claims 21, 41, and 56 as reading on the Marnay device, which lacks the recited attributes when assembled.

For the foregoing reasons, claims 21, 41, and 56 distinguish over Marnay. Necessarily, each claim depending directly or indirectly on claim 21, 41, or 56 also distinguishes over Marnay. The withdrawal of the rejections of claims 21-23, 30, 34, 41, 42, 46-49, 52, 56, 57, 61, and 64 based on Marnay is thus respectfully requested.

## Rejection of Claims 21, 22, 29, 33, 41, 47, 50, 56, 62, and 63 Based on Pisharodi

Independent claims 21, 41, and 56 have been amended to recite that the core has a curved upper surface and the upper plate has a curved lower surface. This arrangement has advantages, some of which are discussed in the specification. Pisharodi does not disclose a core having a curved upper surface or an upper plate having a curved lower surface. Accordingly, amended claims 21, 41, and 56 distinguish over Pisharodi. Necessarily, each claim depending directly or indirectly on claim 21, 41, or 56 also distinguishes over Pisharodi. The withdrawal of the rejections of claims 21, 22, 29, 33, 41, 47, 50, 56, 62, and 63 based on Pisharodi is thus respectfully requested.

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Rejection of Claims 24-26, 31, 32, 38, 40, 43-45, 51, 53-55, and 58-60 Under 35 U.S.C. § 103(a)

Claims 24-26, 31, 32, 38, and 40 depend directly or indirectly from claim 21. Claims 43-45, 51, and 53-55 depend directly or indirectly from claim 41. Claims 58-60 depend directly or indirectly from claim 56. As discussed above, the rejections of amended independent claims 21, 41, and 56 are unfounded and must be withdrawn. Thus, the rejections under 35 U.S.C. § 103(a) of the claims depending directly or indirectly from claims 21, 41, and 56—i.e., claims 24-26, 31, 32, 38, 40, 43-45, 51, 53-55, and 58-60—is respectfully requested.

## Conclusion

In view of the reasons given above, reconsideration of the pending application and the timely allowance of pending claims 21-64 are respectfully requested.

It is believed that this paper addresses all of the rejected claims and other matters sufficiently to support the allowance of all of the pending claims. The December 26, 2007, Office action contains a number of statements potentially reflecting characterizations of various claims, supporting descriptions, and/or patent or patent application references, but regardless of whether any such statements are addressed in this response, the Principal (as defined in 37 C.F.R. § 1.32(a)(3)) declines to automatically subscribe to any statement or characterization in the Office action. Although the Examiner's rejection of claims 21-64 has been traversed as set forth above without reference to many of such statements, all rights to dispute statements regarding such rejections later in any subsequent applications or causes of action relating to this application or any other application are expressly reserved. Accordingly, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as conceding any issue with regard to any claim except as specifically and expressly stated in this

In particular, the Examiner's rejections of the dependent claims have not been addressed herein apart from their respective independent base claims, but all rights to dispute statements regarding such rejections later in this or any subsequent applications or causes of action relating to this application or any other application are expressly reserved.

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paper, and the amendment of any claim should not be construed as conceding the unpatentability of the claim prior to amendment except as specifically and expressly stated in this paper.

The Commissioner is hereby authorized by this written request to treat this or any concurrent or future reply that requires a petition for an extension of time under 37 C.F.R. § 1.136(a) for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The Commissioner is further authorized to charge all required fees, including without limitation excess claim fees or other fees under 37 C.F.R. § 1.16 or any required extension of time fees or other fees under 37 C.F.R. § 1.17, to Deposit Account No. 06-1050, on which the undersigned is authorized to sign, and to treat such authorization to charge Deposit Account No. 06-1050 as a constructive petition for an extension of time in this or any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136(a) for its timely submission. The Commissioner is further hereby authorized to credit any overpayment to Deposit Account No. 06-1050.

Please direct all correspondence in this application to PTO CUSTOMER NO: 26201.

Respectfully submitted,

Date: June 25, 2008

SteVe Lauff

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